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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,192	06/24/2002	Beth E. Borowsky	59138-B-PCT-US/JPW/FHB	4898

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,192	BOROWSKY ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *166-173* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *166-173* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/27/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 166-173 are pending in the instant application. Claims 1-14, 19, 36, 47 and 58 have been canceled and claims 166-173 have been added as requested by Applicant in the Paper filed January 22, 2004.

Election/Restriction

2. Applicant's cancellation of all previous claims and submission of new claims 166-173, which are drawn to a single inventive concept different from those of the original claims, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

3. Applicant is reminded of the following requirement:

In a continuation or divisional application (other than a continued prosecution application filed under 37 CFR 1.53(d)), the first sentence of the specification or application data sheet (37 CFR 1.76) should include a reference to the prior application(s) from which benefit of priority is claimed, and also the status. See 37 CFR 1.78. The status of application 09/518,914 and 09/303,593 should be updated (now patent No. 6,413,731 and abandoned, respectively).

Information Disclosure Statement

4. In the statement accompanying the Supplemental Information Disclosure Statement filed May 27, 2003, Applicants state that another Information Disclosure Statement was filed May 14, 2002. However, the May 14, 2002 IDS is not present in the file.

Specification

5.1 The disclosure is objected to because of the following informalities:

37 C.F.R. §1.821(d) states:

> Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Sequences are disclosed in Figures 7, 8, 11 and 12 without the required reference to the sequence identifiers (SEQ ID NOS:). Also, the instant specification may need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. This can be resolved by adding a reference to the Figures or the Brief Description of the Drawings. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

Applicants are required to amend the specification and claims to comply with 37 C.F.R. §1.821(d).

5.2 The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Drawings

6. The Drawings are objected to because Figure 7A (page 14) of the Drawings is missing.

Claim Objections

7. Claims 169 and 173 are objected to because of the following informalities:

7.1 For claim 169, on the fourth line of the claim, the word "of" should be inserted after the word "activation" to be grammatically correct.

7.2 For claim 173, sections (f) and (g) should be labeled (d) and (e).

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 166-173 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-36 of U.S. Patent No. 6,413,731. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in Patent No. 6,413,731 are drawn to a method of screening for compounds that bind to, activate or inhibit the receptor of SNORF36a receptor (SEQ ID NO: 2), and the claims of the instant application are drawn to a method of screening for compounds that bind to, activate or inhibit the receptor of SNORF36a receptor (SEQ ID NO: 2) and admixing a pharmaceutically acceptable carrier. It would be *prima facie* obvious to one of ordinary skill in the art to admix a

pharmaceutically acceptable carrier to a compound that was found to that bind to, activate or inhibit the receptor of SNORF36a receptor, in order to test the compound in an animal model of a disease or disorder, in order to determine the effects of the compound on the animal.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9.1 Claims 166-173 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 166-173 encompass methods for preparing pharmaceutical compositions comprising identifying compounds that bind to, activate or inhibit the receptor of SEQ ID NO: 2 of the instant application, and admixing a pharmaceutically acceptable carrier, or methods for preparing a composition comprising identifying a compound that activates or inhibits the receptor of SEQ ID NO: 2 of the instant application, and admixing a pharmaceutically acceptable amount of the compound with a pharmaceutically acceptable carrier. Thus the claims encompass a "pharmaceutical use" for the compositions. For the claims to be enabled, the specification must teach how to use the composition for at least one pharmaceutical use without undue experimentation. Steadman's Medical Dictionary (24th Edition, 1982) defines "drug" as "a therapeutic agent; any substance other than food, used in the prevention, diagnosis, alleviation,

treatment or cure of disease in man and animal." Ansel et al (Pharmaceutical Dosage Forms and Drug Delivery Systems, Seventh Edition), says "A drug is defined as an agent intended for use in the diagnosis, mitigation, treatment, cure or prevention of disease in humans or in other animals. One of the most astounding qualities of drugs is the diversity of their actions and effects on the body." The following are examples of "pharmaceutical uses": administering vitamin supplements (preventing disease); using labeled antibodies for in vivo imaging (diagnosing disease); administering a substance to alleviate a symptom of a disease (alleviating or treating disease); and administering an antibiotic (curing bacterial infection). Administering a polypeptide to produce antibodies to protect the individual from contracting a disease, i.e., vaccination, is a pharmaceutical use, however, administering a polypeptide to produce antibodies which are then collected from the animal and used in various ways is not a pharmaceutical use.

In the present situation, to enable a pharmaceutical use for the compounds requires the specification to teach how to use the substance, without undue experimentation, for the prevention, diagnosis, alleviation, treatment or cure of a disease in the animal to which the substance is administered. However, the specification does not provide adequate guidance as to how the identified compounds can be used to treat or diagnose any disorders. The SNORF36a receptor of the instant invention is a receptor in the G-protein coupled family of receptors, and is similar to invertebrate opsins, and is hypothesized to be a non-visual opsin, and potentially are involved in physiological processes such as circadian rythyms. It is hypothersized that non-visual opsins may also play a role in seasonal affective disorder. Experiments in the specification demonstrate that cells transfected with the SNORF36a receptor will mobilize calcium in response to light in the absence of any ligand (Fig. 13A), whereas preincubating the

cells with light for 90 minutes photobleaches the receptor and apparently causes photoisomerization of the endogenous ligand, and the receptor cannot mobilize calcium. SNORF36a in Photobleached cells and given exogenous retinal ligands retains the ability to mobilize calcium, and also can hydrolyze phosphoinositide. On pages 66-68 and 111 are listed a number of disorders or diseases that may be treated using an agonist or antagonist of SNORF36a, however, there is no correlation between any of the diseases or disorders and the activity of the SNORF36a receptor. The only data are *in vitro* experiments demonstrating the activity of the SNORF36a receptor in transformed cells as a response to light or retinals. There are no examples of treatment by administration of any agonist or antagonist or SNORF36a. It is not predictable from the in vitro experiments of the instant specification or from the teachings of the prior art that antagonists or agonists of SNORF361 could be used to treat the diseases or disorders asserted in the specification.

Due to the lack of direction or guidance in the specification, the absence of working examples and teachings of the prior art, the unpredictability in the art, and the complex nature of the invention, undue experimentation would be required of the skilled artisan to use a "pharmaceutical composition" comprising an undefined compound that bind to, activate or inhibit the receptor of SEQ ID NO: 2 of the instant application. However, the specification enables a method of preparing "a composition" comprising admixing a pharmaceutically acceptable carrier with a compound that binds to, activates or inhibits the receptor of SEQ ID NO: 2 of the instant application. Deletion of the word "pharmaceutical" in the term "pharmaceutical composition" or deletion of the term "pharmaceutically acceptable amount" in the claims would therefore obviate the rejection.

9.2 Applicants referral to the deposit of plasmid pcDNA3.1-hSNORF36a-f on page 31 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to recite the date of the deposit, the complete name and address of the depository, and the accession number of the deposited cell line is required.

Pertinent Art

10. The art made of record and not relied upon is considered pertinent to applicant's disclosure. Burmer et al., U.S. Patent Application Publication No. 20030113798, which discloses a polypeptide (SEQ ID NO: 603) which is 100% identical the polypeptide of SEQ ID NO: 2 of the present application. This is not considered prior art, as the effective priority date of that application is after the effective priority date of the instant application.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (571) 272-0871.

Official papers Before Final and After Final filed by RightFax should be directed to (703) 872-9306.

The customer service RightFax number is (703) 872-9305.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Eileen B. O'Hara, Ph.D.

Patent Examiner